Re:K122221

MAR 2 9 2013

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

The Assigned 510(k) number is: _____

1. Submitter's Identification:
   TaiDoc Technology Corporation
   3F, 5F, No.127, Wugong 2nd Rd., Wugu District, New Taipei City, 248, Taiwan

   Correspondence:
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   Regulatory Affairs Specialist
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   Date of submission: JUL 23, 2012

2. Device name:
   Proprietary name: Nexus IR30 Thermometer

   Regulatory information:
   A. Regulation section: 21 CFR 880.2910
   B. Classification: Class II
   C. Product Code: FLL, Clinical electronic thermometer
   D. Panel: General Hospital (80)

3. Intended Use:
   Nexus IR30 Thermometer is an electronic thermometer using an infrared sensor to detect human body temperature from the surface of human skin without contact. It is for use by people of all ages in the homecare environment.

4. Device Description:

Nexus IR30 Thermometer is characterized by measuring human body temperature from the surface of human skin. It utilizes infrared technology to measure infrared energy emitted from the skin surface when making a temperature measurement.

Substantial Equivalence Information:

A. Predicate device name:

U-RIGHT TD-1240 Thermometer, model TD-1240

B. Predicate K number: k113159

C. Comparison with predicate:

The Nexus IR30 Thermometer is substantially equivalent to the predicate device U-RIGHT TD-1240 Thermometer (k113159) made by TaiDoc Technology Corporation, for the following reasons:

1) It has the same Indications for use as the predicate.
2) It has the same operating principle and fundamental scientific technology as the predicate.
3) It has the same basic circuit design as the predicate.
4) It incorporates the same materials.
5) It has the same shelf life.
6) It packaged using the same materials.
7) It manufactured by the same process.
8) It has same memory storage capacity.

The Nexus IR30 Thermometer has some minor changes from the predicate device that include:

(1) The Measuring Range has been change from "73.4°F to 111.2°F" to "89.6°F to 109.4°F".
(2) The Operating temperature has been change from "50°F to 104°F" to "60.8°F to 104°F".
(3) The Storage temperature range has been change from "-4°F to 140°F" to "-13°F to 131°F".
(4) The power down time has been changed from 3mins to 15 seconds.
(5) Change in battery type from 1.5V AA to 1.5V AAA.
(6) LCD Backlight changes from blue to white.

(7) The indication icon of the 3-color LED is added.
(8) Changed the physical appearance.
(9) Labeling change due to the modifications

These changes have been verified and validated (as part of performance testing) and are included as part of this submission. A summary of these verification and validation activities is attached. These changes raise no new issues of safety and effectiveness.

5. Test Principle:
The thermometer measures temperature by reading infrared radiation emitting from the skin and converts it into a temperature value.

6. Performance Characteristics:
Nexus IR30 Thermometer has the same performance characteristics as the predicate device.

A comparison of system accuracy performance demonstrated that Nexus IR30 Thermometer and U-RIGHT TD-1240 Thermometer (cleared under k113159) are substantially equivalent.

Software verification and validation, performance and safety tests confirmed that the performance, safety and effectiveness of the Nexus IR30 Thermometer are equivalent to the predicate device.

7. Conclusion:
Based on the information provided in this submission, the Nexus IR30 Thermometer is substantially equivalent to the predicate U-RIGHT 1240 Thermometer, model TD-1240.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Ms. Pinjung Chen
Regulatory Affairs Specialist
TaiDoc Technology Corporation
6F, No. 127, Wugong 2nd Rd., Wugu District,
New Taipei City, Taiwan 24888

March 29, 2013

Re: K122221
Trade/Device Name: Nexus IR30 Thermometer
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: March 13, 2013
Received: March 15, 2013

Dear Ms. Chen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: **K122221**

Device Name: Nexus IR30 Thermometer

Indications for Use:

Nexus IR30 Thermometer is an electronic thermometer using an infrared sensor to detect human body temperature from the surface of human skin without contact. It is for use on people of all ages (infants, children, adolescents, and adults) in the homecare environment.

Prescription Use _____ And/Or Over the Counter Use __X____.
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Keith G. Marin Digitally signed by Keith G. Marin
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Keith G. Marin, 0.9.2342.19200300.100.1.1=0011250397
Date: 2013.03.27 14:08:07 -04'00'

Division Sign-Off
Office of Device Evaluation (ODE)
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